REMARKS

Claims 18-20 and 32-38 are currently pending in this patent application. Applicants gratefully acknowledge the withdrawal of the rejection pursuant to 35 U.S.C. § 103(a) in the Office's communication of 8/24/2005.

Rejection under 35 U.S.C. § 103 – Alleged Obviousness

Claims 18-20, 32, 33, 35, 36, and 38 stand newly rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,248,310 ("the Barclay patent") in view of U.S. Patent No. 5,785,994 ("the Wong patent") in further view of U.S. Patent No. 5,294,770 ("the Riddle patent"). Applicants respectfully traverse the rejection because combination of the respective teachings of these patents, even if motivated, would not have produced any claimed method.[1]

Each of claims 18-20, 32, 33, 35, 36, and 38 is directed to methods that involve, *inter alia,* the steps of: (1) compressing a first layer containing a drug ingredient, a second layer containing a drug ingredient, and a third layer that does not contain a drug ingredient, thereby forming a "drug/drug/no drug" three-layer structure; and (2) detecting the formulation orientation of a tablet using a color detector directed at a spot location on the side of the tablet.

A person of ordinary skill seeking to combine the cited teachings of the Barclay, Wong, and Riddle patents would not have produced such a method. The Office Action fails to identify any disclosure in the patents relating to a tablet having dual drug-containing layers, and a drug/drug/no drug orientation three-layer tablet structure, or of using a color detector to detect the formulation orientation of such a tablet. Thus, these aspects of the

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1 With respect to the issue of motivation, the Office Action misstates the requirements for establishing a *prima facie* case of obviousness. Although the Office Action asserts that "for obviousness under § 103, all that is required is a reasonable expectation of success" (Office Action at page 7), much more is required. Specifically, an examiner seeking to enter a rejection for alleged obviousness must additionally identify some suggestion or motivation to combine references or otherwise modify their teachings. MPEP § 2142.

claims would be absent from any method that those of ordinary skill might theoretically produce by combining the patents' cited teachings.

The cited patents also lack disclosure of Applicants' formulating step. Acknowledging that the dosage form disclosed by the Barclay patent has a different structure than those produced by Applicants' claimed methods, the Office Action alleges that it would have been obvious to those of ordinary skill to instead employ the structure disclosed by the Wong patent (Office Action at page 4). Significantly, however, although the Wong patent discloses a three-layer dosage form, the orientation of those layers differs from the orientation recited in the instant claims. Furthermore, there is no disclosure at all of the use of two drug layers, as recited in the instantly rejected claims. The Office Action, for example, refers to the dosage form described at column 17, which has a "no drug/drug/no drug" structure that is said to be formed by disposing a *single* drug-containing layer between two layers that do not contain a drug (Wong patent at column 17, lines 34-43). Thus, whereas the claimed methods yield a "drug/drug/no drug" structure, the proposed combination of the Wong and Barclay patents would yield a *different* structure, having the "no drug/drug/no drug" orientation.

The Office cites the Riddle patent for the proposition that using a color detector is recognized in the art, but combination of the Wong and Barclay patents with the Riddle patent would not supply the missing "drug/drug/no drug" orientation or the two drug-containing layers structure.

Since combination of the Wong, Barclay, and Riddle patents would not have produced any of the claimed inventions, the rejection for alleged obviousness is improper and should be withdrawn. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974) (all limitations set forth in a patent claim must be taught or suggested in the prior art to establish a prima facie case of obviousness).

Conclusions

In view of the above, applicants respectfully request reconsideration and withdrawal of the rejection of claims 18-20 and 32-38, as well as allowance thereof. If the Examiner is of a contrary view, the Examiner is invited to contact the undersigned attorney at (215) 568-3100.

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